

REMARKS

This amendment is responsive to the Office Action of February 14, 2001. Reconsideration of claims 1-22 is respectfully requested.

The Office Action

Claims 1, 3, 15-16, and 21 stand rejected under 35 U.S.C. § 112 second paragraph, as being indefinite.

Claims 1-21 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over **Minerovic, et al.** (U.S. Patent No. 5,997,814) in view of **Malchesky, et al.** (U.S. Patent No. 5,518,927).

35 U.S.C. § 112

Applicants submit that the phrase "sufficient period of time" in claims 15 and 16 is not unclear. As indicated in the specification, the time taken to effect decontamination depends on a number of factors, including the temperature, the level of decontamination required (e.g., sterilization or high level disinfection), and the like. One skilled in the art is familiar with the methods for determining what a sufficient period of time would be, for example, by subjecting a series biological indicator to the cycle and determining how long it takes for the desired level of kill. Thus, the time taken for the color change of the indicator can vary.

The applicants have carefully amended the claims to address each of the other points raised by the Examiner. It is submitted that all claims now comply fully with the requirements of 35 U.S.C. § 112.

**The Minerovic Reference is not Properly a Reference
Against the Claims of the Present Application**

The Minerovic, et al. patent is not properly a reference under 103(a)/102(e) since it falls under the provisions of 103(c). The Minerovic patent issued in December 1999, after the filing date of the present application. The present application was assigned to STERIS

Corp. and the inventors were under an obligation to assign to STERIS Corp. at the time the invention was made. The Minerovic, et al. patent was also assigned to STERIS Corp., and was so assigned at the time the invention of the present application was made. Accordingly, applicants respectfully request that the Minerovic, et al. patent be removed as a reference. Malchesky, et al. fails to disclose or fairly suggest the presently claimed invention.

Claims 8, 15 and 19 have been amended and placed in independent form to provide differences in scope of the claims, and not for any reasons related to patentability.

Accordingly, it is submitted that claims 1-22 are now in condition for allowance.

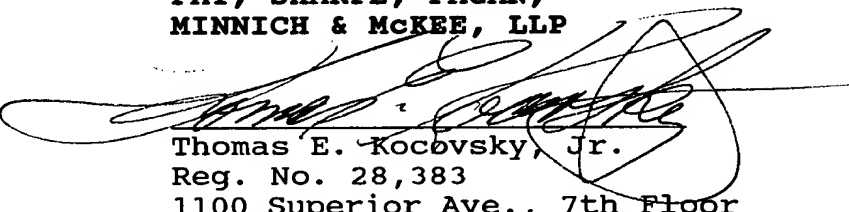
Formal Drawings

The applicants note the PTO-948 indicating that the informal drawings filed with the application are informal. However, Formal Drawings were filed in July 2000. An indication that the July 2000 Drawings are acceptable is again requested.

CONCLUSION

For the reasons set forth above, it is submitted that claims 1-22 distinguish patentably and unobviously over the references of record. An early allowance of all claims is earnestly solicited.

Respectfully submitted,
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VERSION OF CLAIMS WITH MARKINGS TO SHOW CHANGES MADE

April 19, 2001

Please amend claims 1 and 3, as follows:

1. (Amended) A single-use package for holding a powdered composition which forms a solution of an anti-microbial decontaminant when mixed with water and for [selectively] releasing the composition when the package is
5 opened or when the composition dissolves and passes through
a porous portion of the package, the package comprising:
 - a porous portion which is impermeable to the powdered composition but is permeable to water and to the solution; and,
 - 10 an indicator on the porous portion which exhibits a detectable change on exposure to the decontaminant in the solution.
3. (Amended) The package of claim 2, wherein the cartridge further includes:
 - an outer, first cup including a first peripheral wall with an opening at an end, the first peripheral wall
5 being at least selectively water transmissive;
 - an inner, second cup including a second peripheral wall, the second peripheral wall having a detachable portion
[being at least selectively water transmissive], the first and second cups being configured such that the second
10 peripheral wall abuts and is connected to the first cup adjacent the end of the first peripheral wall;
 - a top cover covering the openings in the first and second cups, such that the first compartment is defined in the first cup and the second compartment is defined in the
15 second cup.

Please add new claim 22, as follows:

22. (New) The package of claim 2, wherein the package further includes:

an outer, first cup including a first peripheral wall with an opening at an end, the first peripheral wall
5 being at least selectively water transmissive;

an inner, second cup including a second peripheral wall, the second peripheral wall having a water permeable portion, the first and second cups being configured such that the second peripheral wall abuts and is connected to
10 the first cup adjacent the end of the first peripheral wall;

a top cover covering the openings in the first and second cups, such that the first compartment is defined in the first cup and the second compartment is defined in the second cup.

Please amend claims 4 and 6, as follows:

4. (Amended) The package of claim [3] 22, wherein the first peripheral wall includes a region which is formed from a first material which is impermeable to the first component but is permeable to water and to solutions
5 containing dissolved components.

6. (Amended) The package of claim [3] 22, wherein the second peripheral wall includes a region which is formed from a second material which is impermeable to the first and second components but is permeable to water and to
5 solutions containing dissolved components.

Please place claim 8 in independent form, as follows:

8. (Amended) [The] A single use package [of claim 3, wherein the] for holding a dry composition which

forms an anti-microbial solution when mixed with water, the package comprising:

- 5 a side wall;
 a bottom wall across a lower portion of the
 sidewall;
 a top cover across an upper portion of the side
 wall, the top cover defining a [defines the] porous portion
10 which is impermeable to the dry composition but is permeable
 to water and to the solution; and
 an indicator on the top cover which exhibits a
 detectable change on exposure to the anti-microbial
 solution.

Please place claim 15 in independent form, as follows:

15. (Amended) [The] A package [of claim 1, wherein the] for holding an anti-microbial concentrate which forms an anti-microbial solution when mixed with water, the package releasing anti-microbial concentrate at a selected
5 time in an anti-microbial cycle, the package comprising:
 a porous portion which is impermeable to the anti-microbial concentrate but is permeable to water and to the solution; and
 an indicator on the porous portion which exhibits
10 a detectable color change when exposed to a [sufficient] preselected minimum concentration of the decontaminant for a [sufficient] preselected minimum period of time to indicate the formulation of an anti-microbial solution capable of effecting anti-microbial decontamination.

Please place claim 19 in independent form, as follows:

19. (Amended) An anti-microbial system [which receives the package of claim 1] comprising:

a well for receiving [the] a single use package
[of claim 1;] including:

5 at least one cup which holds an anti-
 microbial concentrate,

a porous portion which is permeable to
 water and to an anti-microbial solution formed
 from the anti-microbial concentrate and the water,
10 and

an indicator on the porous portion which
 exhibits a detectable change on exposure to a
 decontaminant in the solution;

 a source of water connected with the well for
15 mixing with the [powdered composition to] anti-microbial
 concentrate and forming the anti-microbial solution;

 a microbial decontamination chamber connected with
the well for receiving the anti-microbial solution, the
well, the porous region, and the chamber forming a
20 recirculating fluid flow path for the [decontaminant] anti-
 microbial solution, whereby the recirculating anti-microbial
 solution passes over the indicator.

Please amend claim 21, as follows:

21. (Amended) A method comprising:

 flowing water through a cartridge containing a
composition to form a decontaminant solution from the
composition and the water, the cartridge including a porous
5 region impregnated with an indicator, the indicator
exhibiting a preselected detectable change when contacted
with a decontaminant solution [for a period of time] and at
a concentration of a decontaminant in the solution
sufficient to effect decontamination of items;

10 circulating the decontaminant solution in a fluid
flow path comprising a microbial decontamination chamber, in
which the items to be decontaminated are positioned, and the
porous region;

 examining the indicator for the detectable change.